II. RESPONSE TO OFFICE ACTION

I. Claims in the Case/Preliminary Matters

Claims 4-7 have been withdrawn as directed to non-elected species. Claims 15-33 have been canceled as drawn to non-elected inventions. Claims 34-43 have been added. Support for the new claims can be found in original claims 20-22 and 24-32. It is believed that all of the newly added claims are generic with respect to the Group I species/invention election dated August 30, 2004.

It is noted that the Examiner incorrectly failed to consider claim 3, which is a specific part of the Group I invention elected August 30, 2004. It is specifically noted that the Group I was characterized by the Examiner, in the restriction/election dated July 6, 2004, as being drawn to "a method for determining the effectiveness of a cancer treatment by assaying ***a hair follicle***." (our emphasis). Therefore, the Examiner is requested to examine the elected species as set forth in claim 3.

Claim 1 has been amended to recite the use of a "non-tumor surrogate" tissue sample. Support for this amendment can be found in the specification at page 60, line 67, and is implicit throughout the specification. It is intended that this amendment to claim 1 clarify that claim 1 is directed to the testing of non-tumor tissue samples, as this is one of the recognized advances of the present invention – that one can test non-tumor tissues obtained by non-invasive means to test the effectiveness of the therapy. If the Examiner would prefer some other wording to relate this concept in claim 1, he is respectfully requested to make a suggestion.

II. Rejections Under 35 U.S.C. §112, First Paragraph

The Action first rejects all of the pending claims under 35 U.S.C. §112, first paragraph, taking the position that the specification is inadequately enabled as to the scope of the claims.

The Action takes the position that the claims are enabled only for cancers expressing the growth factor and treatments directed to the growth factor.

Claim 1 is now directed to cancer treatments that are designed to change growth factor receptor phosphorylation, which should address the Examiner's concerns. We have not specified that claim 1 requires that the cancer itself necessarily be growth factor receptor positive *per se*. The reason for this is at least two-fold: one, physicians are the ones that will make the decision about the applicability of a particular treatment, and if the treatment is "designed to change growth factor receptor phosphorylation," then presumably the physician has concluded that the cancer is one that is likely (but is not necessarily) growth factor related. Second, the claimed assay will necessarily and inherently make the determination that the cancer is growth factor related, if indeed it is.

The Examiner is thus requested to reconsider and withdraw the rejection.

III. Rejections under 35 U.S.C. §103(a)

Lastly, the Action rejects all of the claims as obvious over either of two Pollack *et al.* references taken in light of Scardino *et al.* and the two Prewett *et al.* articles, for the reasons recited on pages 6-9 of the Action. Applicants respectfully traverse. (For the Examiner's convenience, a complete copy of each of the cited references is enclosed.)

It is the Applicants' position that the Action fails to set forth a *prima facie* obviousness rejection. For example, the Action fails to point to any prior art that teaches or suggests testing growth factor receptor phosphorylation of a tissue obtained by a non-invasive procedure. While the Scardino *et al.* abstract makes reference to a "needle biopsy" it appears that this reference is simply directed to using the needle biopsy to assess cellular structures of tumors (rather than surrogate tissues) to determine the effectiveness of certain therapy of prostate cancer. We can

find no reference here to, for example, therapies directed to growth factor receptors, growth factor receptor assays or phosphorylation assays or the testing of surrogate tissues.

The Action notably fails to explain exactly how this reference is in any way combinable with references that teach enzymatic and other "assays" that are to be performed on tissues. Thus, the Action has failed to show how this reference is in any way combinable with other art to raise a *prima facie* rejection.

Furthermore, it is noted that Pollack *et al.* (1999) apparently employed fairly substantial amounts of tissue to carry out its assays, including tumors that were "5-10 mm in diameter" that were excised (*ie.*, surgically removed) , flash frozen, homogenized, *etc.*, and then subject to extensive handling prior to assay. Thus, there is neither motivation nor reasonable expectation of success shown for one of skill from the vantage point of Pollack *et al.* to apply such a procedure to a non-surgically obtained needle biopsy. It is particularly noted in this regard that the needle biopsy of Scardino *et al.* was simply to assess cellular structure and cytology – that's what a "biopsy" is – and was not employed for a biological assay as far as can be determined from the abstract. Thus, the references have not been shown to be combinable and no *prima facie* rejection made on this record. "The mere fact that references can be combined or modified does not render the resultant combination obvious ***unless the prior art also suggests the desirability of the combination***." MPEP § 2143.01 (emphasis added). None of the references relied upon by the Examiner has been shown to suggest the desirability of conducting the claimed assay on a tissue obtained by a non-invasive procedure from a patient undergoing growth factor receptor therapy.

The Examiner is thus requested to reconsider and withdraw the subject obviousness rejection.

IV. Conclusion

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

Should the Examiner desire to sustain any of the rejections discussed in relation to this Response, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3055 is respectfully requested.

Respectfully submitted,

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